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Administrative Measures on Novel Foods (revised version)

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Report Highlights:
This is an UNOFFICIAL translation of China's Administrative Measures on Novel Foods (revised version), which was notified to the WTO on February 21, 2007. Interested parties are welcome to provide comments on this regulation within 60 days of notification.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Beijing [CH1]
[CH]

Executive Summary
China notified the WTO of T*he Administrative Measures on Novel Food (revised version)* under G/TBT/N/CHN/240 on February 21, 2007. The document stipulates the definition, safety assessment, application and approval process, production management, and hygienic inspection of novel foods in China. These Measures do not cover genetically modified (GM) food and food additives, which are regulated separately.

According to the regulation, production and import of novel food are subject to pre-approval by China's Ministry of Health.

The following is an unofficial translation of the notified TBT measure that is open for comment within 60 days of circulation by the WTO Secretariat. China has not set an adoption date for the regulation.

BEGIN TRANSLATION

Administrative Measures on Novel Food (Revised Version)

Chapter 1 General Provisions

Article 1 These Measures are formulated in accordance with the *Food Hygiene Law of the People's Republic of China*, with an aim of strengthening the supervision and administration of novel food, and safeguarding the health of consumers.

Article 2 Novel food referred in the Measures includes:
(1) Animals, plants and microorganisms that are not traditionally consumed in China;
(2) Raw food materials that are derived from animals, plants and microorganisms and are not traditionally consumed in China;
(3) New varieties of microorganisms that are used during food processing;
(4) Raw food materials the original composition or structures of which are changed by the adoption of new techniques during production.

Article 3 The Ministry of Health is responsible for the supervision and administration of novel food hygiene at the national level.
Health administrative departments of local people's governments at the county level or above are responsible for the supervision and administration of novel food hygiene within their jurisdiction.

Article 4 The government encourages scientific research and development of novel food.

Chapter 2 Safety Assessment

Article 5 Novel food shall comply with the *Food Hygiene Law of the People's Republic of China*, pertinent regulations, rules and standards, and shall not cause any acute, subacute, chronic or other latent health hazards.

Article 6 The Ministry of Health shall establish a food safety assessment system for novel food. Food safety assessment of novel food shall follow the principles such as risk assessment and substantial equivalence.
The Ministry of Health formulates and promulgates safety assessment regulations, technical specifications and standards of novel food.

Article 7 The Expert Assessment Committee on Novel Food of the Ministry of Health (hereinafter referred to as the Assessment Committee) is responsible for safety assessment

of novel food. The Assessment Committee is composed of experts in fields of food hygiene, toxicology, nutrition, microorganisms, processing techniques, chemistry, pharmacology, etc.

Article 8 The Assessment Committee shall exercise its safety assessment on the basis of the following materials and data: source of novel food, traditional consumption history, processing techniques, quality standards, main ingredients and contents, estimated intake, usage and scope of application, toxicology, biological features, genetic stability, pathogencity and toxicity of strains of microbiological products and other scientific data.

Article 9 In case of any of the following circumstances, the Ministry of Health may organize the Assessment Committee to reassess the approved novel food:

(1) With the development of science and technology, recognition of food safety and nutrition about approved novel food have changed;

(2) Challenges raised against food safety and nutritional quality of novel food;

(3) As required by supervision and monitoring of novel food.

In case the approved novel food fails to pass the reassessment, the Ministry of Health may announce prohibition on production, business operation and use of the food.

Chapter 3 Application, Review and Approval

Article 10 Novel foods are subject to safety assessment, and reviewed and approved by the Ministry of Health before they are marketed for the first time.

Article 11 Applications for novel food at the Ministry of Heath shall include the following materials:

(1) Application for hygiene administration permit of novel food;

(2) Research and production report;

(3) Brief summary and flow chart of processing techniques;

(4) Product quality standards;

(5) Status on research and production at home and abroad, as well as safety related documents;

(6) Product label and instructions; and

(7) Other materials helpful to assessment and review.

Also, submit a sealed product sample or 30-grams of raw material.

In case of applications for importation of novel food, it is also required to submit certificates indicating the production (or marketing) of the food products are permitted in the exporting country (region) or documents showing the traditional consumption history of the food in the exporting country (region), which are issued by relevant departments or institutions of the exporting country (region).

Article 12 After accepting applications for novel foods, the Ministry of Health organizes the Assessment Committee to conduct preliminary technical examination. In case additional or corrective materials are needed, the applicant shall cooperate.

After the preliminary technical examination, the Assessment Committee shall determine the safety test items, test sample batches, test methods and testing institutions of the novel food, and decide on whether to conduct on-site examination and collect and seal samples, and inform the applicant. Generally, testing institutions accredited by the Ministry of Health shall carry out the safety tests.

In case on-site examination and collection of sealed samples is required, the applicants of domestically-produced novel foods shall file an application to the local health administration department at the provincial level who shall organize implementation of such on-site examination, collection and sealing of samples. Applicants of imported novel foods shall file the applications to the Ministry of Health, who organize the implementation (of the on-site examination, collection and sealing-up of samples).

Article 13 Based on the conclusion of the technical examination of the Assessment Committee and the results of the on-site examination, the Ministry of Health shall conduct an administrative review and decide on whether to approve the novel food. After the review, the Ministry of Health shall inform the applicant if the novel food is considered a regular food.

Article 14 The Ministry of Health shall publish the list of approved novel foods, which, based on characteristics of different novel foods, should cover contents such as generic name (including Latin name), species, source, biological characteristics, adopted techniques, main ingredients, edible parts, dosage level, scope of application, ethnical group of application, intake amount, and quality standards; for microorganisms, their strain numbers shall also be indicated.

Article 15 In line with the use of novel food, the Ministry of Health shall timely announce the list of novel foods that are considered as regular foods.

Article 16 Specific procedures for examination and approval of novel food shall be in compliance with pertinent provisions, such as the *Administrative Measures on Hygiene Administration Permits* and the *Procedures on Hygiene Administration Permit*.

Article 17 An applicant of novel food can be a citizen, legal person or organization.

Chapter 4 Production, Operation and Administration

Article 18 Food manufacturing and operating enterprises shall ensure food safety of the novel food they manufacture, operate and/or use.

Foods listed in Article 2 of the Measures but not yet approved and published as novel foods by the Ministry of Health shall not be manufactured, operated or used as food or raw food materials.

Article 19 Novel food manufacturers must comply with provisions and requirements set forth in relevant laws, regulations and technical norms.

Manufacturers shall apply for and get a hygiene permit at the health administration department at provincial level before production of a novel food.

Article 20 Food manufacturers shall verify the Ministry of Health's announcement and make sure their products are substantially equivalent with the announced items before they start manufacturing or using the novel food.

Article 21 Enterprises manufacturing novel foods or using novel food to produce other foods shall establish a collection and reporting system on novel food safety information, and make annual reports on novel food safety information to the local health administration departments. If food safety problems are found associated with the novel food, the enterprise shall timely report to the local health administration departments.

Consumers encountering food safety problems may report to the local health administration departments.

Article 22 Novel foods or food products containing novel foods shall be labeled in compliance with relevant government regulations and names indicated in the labels shall be identical to that announced by the Ministry of Health.

Article 23 Enterprises manufacturing, operating and/or using novel foods shall not claim or imply the therapeutic effects and health functions of the novel food.

Chapter 5 Hygiene Supervision

Article 24 Health administrative departments of the people's governments at the county level or above shall conduct supervision, random inspections and daily hygiene supervision and administration of the production, operation and use of novel food in accordance with the *Food Hygiene Law of the People's Republic of China* and relevant regulations.

Article 25 Health administrative departments of the people's governments at the county or city (with districts) level and shall regularly inspect the information collection and reporting regarding novel food safety and timely report to the health administrative departments at provincial level the food safety information about novel food within their jurisdiction. The health administrative departments at provincial level shall investigate, confirm and handle the reported food safety information and report to the Ministry of Health on a regular basis. The Ministry of Health shall regularly gather food safety information about novel food, make timely announcements to the public, and, if necessary, issue early warnings or reassess the novel food that has food safety problems.

Enterprises manufacturing or operating novel food shall cooperate with the health administrative departments in investigating and handling food safety issues. In case of concealing food safety information, the health administration departments may issue a public complaint.

Article 26 Manufacturing or operating novel food that is not approved by the Ministry of Health or using novel food that is not approved by the Ministry of Health as a raw material for food processing, the enterprise shall be penalized by the health administrative department of the people's government at the county level or above in accordance with Article 42 of the *Food Hygiene Law of the People's Republic of China*.

Article 27 Violators of the *Food Hygiene Law of the People's Republic of China* or other relevant hygienic requirements shall be penalized accordingly.

Chapter 6 Supplementary Provisions

Article 28 Definitions of the following terms:

Risk assessment: refers to scientific evaluations on known or potential negative effects of food borne hazards which human body exposes to upon human health, including four steps: hazard identification, hazard characterization, exposure assessment and risk characterization.

Substantial equivalence: means that if raw materials or food ingredients of a novel food are substantially equivalent to traditional food or food ingredients or approved novel food in terms of species, source, biological characteristics, main ingredients, edible parts, dosage level, scope of application and group of application, and their processing techniques and quality standards adopted are basically identical, the novel food is considered equally safe as the traditional counterpart and has substantial equivalence.

Article 29 The administration of GM food and food additives is subject to relevant State laws and regulations.

Article 30 These Measures will come into force as of _____, 200_, and the *Administrative Measures on Novel Food Hygiene* and the *Administrative Measures on GM Food Hygiene*, promulgated by the Ministry of Health on July 28, 1990 and April 8, 2002, respectively, shall be repealed at the same time.

END TRANSLATION